

Appl. No. : 10/031,021
Filed : March 19, 2002

REMARKS

The Specification has been amended. Support for the amendments can be found, for example, on page 9 lines 3, 18 and 19 of the Specification as filed. Claims 2, 3, and 5 have been canceled. Claims 1, 4, 6, 7, and 10 have been amended. Support for the amendments can be found in canceled claims 2 and 5. New Claims 14 and 15 have been introduced. Support for the new claim can be found in the Specification as filed, for example, on page 8 paragraph [0026] and pages 9-11 paragraph [0027]. No new matter has been introduced with these amendments. As a result, claims 1, 4, 6, 7, 9-14 are pending. The following addresses the substance of the Office Action.

Claim rejections under 35 U.S.C. §112

The Examiner has rejected Claims 1-7 and 10 under 35 U.S.C. §112, first paragraph as lacking written description of a representative number of transgenic species of non-human mammals as claimed. Furthermore, Claims 1-7 and 10 were rejected under 35 U.S.C. §112, first paragraph as non-enabled for producing any other non-human mammal with a disrupted AFP gene, except for a female mouse. The Applicants have amended Claims 1, 4, 6, 7, and 10 to recite "a sterile female genetically modified mouse". Such amendment is supported in the Specification as filed, for example, on page 9, paragraph [0027], and in canceled claims 2 and 5. Applicants reserve the right to pursue claims which are not limited to mammals other than female mice in related applications.

The Examiner has rejected Claim 1 under 35 U.S.C. §112, second paragraph as being indefinite in recitation of "the genetic sequence encoding the wild-type alpha-fetoprotein (AFP)". More specifically, the Examiner asserted that this term lacks the antecedent basis. Applicant has amended Claim 1 to recite: "deletion in endogenous genetic sequence encoding the wild type alpha-fetoprotein (AFP)". Support for the amendment can be found throughout the Specification, for example, on page 12, paragraph [0034]. Therefore, Claim 1 is now definite, and its rejection 35 U.S.C. §112, second paragraph should be withdrawn.

Claim rejections under 35 U.S.C. §102

The Examiner has rejected Claims 1-4 as being anticipated by Jin *et al.* 1998 PNAS, 95:8767-8772, or Cirillo *et al.* 1995 Developmental Biology 168:395-405. More specifically, the Examiner has rejected these claims because both Jin *et al.* and Cirillo *et al.* allegedly teach a

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genetically modified mouse which comprises a partial deletion of a genetic sequence encoding a functionally active alpha-fetoprotein. Applicants respectfully disagree.

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Jin *et al.* and Cirillo *et al.* both teach a mouse comprising a transgenic AFP with a specific deletion in that gene or its repressor element. Neither Jin *et al.* nor Cirillo *et al.* teach that a mutation, a partial deletion or a total deletion is introduced in endogenous genetic sequence encoding the wild type alpha-fetoprotein (AFP) thereby producing a sterile female. Therefore, Jin *et al.* and Cirillo *et al.* do not anticipate currently amended Claims 1 and 4. Jin *et al.* and Cirillo *et al.* also do not anticipate the new Claim 14. Withdrawal of the rejection of Claims 1-4 under 35 U.S.C. §102 is specifically requested.

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CONCLUSION

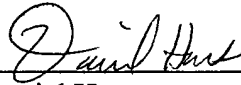
Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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